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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,126	06/22/2001	Jennifer L. Schmitke	2685.2030-000	9053
7590	01/11/2005		EXAMINER	
ELMORE CRAIG, P.C. 209 MAIN STREET NO. CHELMSFORD, MA 01863		HAGHIGHATIAN, MINA		
		ART UNIT		PAPER NUMBER
		1616		

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/888,126	SCHMITKE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Mina Haghigian	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 27 September 2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,3-18,20-39 and 41-60 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 3-18, 20-39, 41-60 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Receipt is acknowledged of the request for reconsideration filed 09/27/04. No claims amended, added or deleted. Accordingly claims 1, 3-18, 20-39, 41-60 are pending.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 3-18, 20-39 and 41-60 under 35 U.S.C. 103(a) as being unpatentable over Patton et al (5,997,848) in view of Edwards et al (5,985,309) is maintained.

### ***Double Patenting***

The provisional rejection of claims 1, 3-18, 20-39 and 41-60 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/179,463 in view of Patton et al (5,997,848) is maintained.

### ***Response to Arguments***

Applicant's arguments filed 09/27/04 have been fully considered but they are not persuasive.

Applicant argues that the invention is to a very specific formulation consisting of approximately 60% DPPC, 30% insulin and 10% sodium citrate. Properties achieved by this specific formulation are not taught by any reference, taken alone or in any

combination. Applicant believes that neither Patton nor Edwards teach that the substitution of DPPC for another excipient, such as sugar or amino acid, would be expected to result in a rapid release product.

The arguments are not persuasive because Patton teaches formulations and method of treating patients comprising insulin in the range of 5 to 95% and preferably 20 to 80%, a buffer such as sodium citrate (usually in the 10-13% range) and a carrier such as amino acids or sugars (usually in the 60-70% range) for inhalation delivery to individuals in need thereof (see col. 3, lines 47-50 and col. 11, lines 16-20). Edwards teaches the addition of DPPC in an amount of about 60% to insulin formulations. Edwards also discloses that phospholipids such as DPPC are EXEMPLARY surfactants and that particles can be effectively aerosolized for administration to the respiratory tract to permit systemic or local delivery of wide variety of therapeutic agents. Formation of complexes of positively or negatively charged therapeutic agents with molecules of opposite charge can allow control of the release rate of the agents into the blood stream following administration (see abstract).

Thus one of ordinary skill in the art, given the advantages of using phospholipids in pulmonary formulations, especially with proteins such as insulin, as disclosed by Edwards, would be motivated to modify the insulin formulations of Patton to include suitable amount of DPPC.

Applicant states that the Declaration was dismissed by the examiner and that the "argument is not fully understood". The Declaration was not dismissed. However it was not found persuasive because while it provided data on the stability of certain

concentration ranges, it did not overcome the prior art rejections. While applicant insists that the specific amounts of each ingredient makes the formulations stable, the concentration ranges fall within the ranges disclosed by the references and thus it is considered that the prior art of record meets the claimed limitations. It is also noted that "stability" is a property of the formulations. The claims are drawn to formulations comprising insulin, DPPC and sodium citrate in specific amounts and a method of treating a patient and a method of delivering the said formulation, all of which was disclosed by the combined references.

Applicant with regards to the double patenting rejection, argues that the instant claims and the claims of the co-pending application No. 10/179,463 do not overlap. This is not persuasive and the rejection is maintained. The claims of the co-pending application and the instant claims are identical except for the small differences in the concentrations of insulin and DPPC. While applicant argues that the relative amounts of components have substantial impact upon the properties of the product, the major argument here is "stability" of the formulations and as shown in the Declaration both amounts of the insulin and DPPC are said to be stable. It is also possible to see the "overlap" by comparing the specification, arguments, Declaration and the claim sets of the two applications.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Gary L. Kunz*  
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Mina Haghigian  
January 07, 2004